IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GOVERNMENT EMPLOYEES HEALTH ASSOCIATION, on behalf of itself and all others similarly situated	*	
Plaintiff,	*	Civil Action No. GLR-18-3560
v.	*	
ACTELION PHARMACEUTICALS Ltd.,	*	
Defendants.		

***

MEMORANDUM OPINION

THIS MATTER is before the Court on Defendants Actelion Pharmaceuticals Ltd., Actelion Pharmaceuticals US, Inc., and Janssen Research & Development, LLC's (collectively, "Actelion") Motion for Summary Judgment (ECF No. 291); Actelion's Motion to Exclude the Damages Opinions and Proposed Testimony of Meredith Rosenthal, Ph.D (ECF No. 287); Actelion's Motion to Exclude the Damages Opinions and Testimony of Todd Clark and Daisy Rivera-Muzzio (ECF No. 289); and Plaintiff Government Employees Health Association's ("Government Employees") Motion to Exclude Certain Opinions of Martin Shimer and Sean Nicholson, Ph.D (ECF No 293). The Motions are fully briefed, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2023).[1] For the

[1] Also pending is the Motion of 69 Professors of Law, Economics, Business, and Medicine for Leave to File an Amicus Curiae Brief (ECF No. 314). There is no Federal Rule of Civil Procedure applicable to motions for leave to appear as amicus curiae in a federal district court. Am. Humanist Ass'n v. Md.-Nat'l Cap. Park & Plan. Comm'n, 303 F.R.D. 266, 269 (D.Md. 2014). Accordingly, district courts have discretion to permit

reasons outlined below, the Court will deny the Motion for Summary Judgment. The Court defers ruling on the pending Daubert motions unless necessary for summary judgment.

I. BACKGROUND

A. Factual Background

The Court provided a complete description of the facts at issue in this case in its September 30, 2019 Memorandum Opinion, (ECF No. 50), which it incorporates here by reference. The Court will not repeat that description in its entirety and will instead provide a brief summary.

Actelion is a pharmaceutical company that produces and sells Tracleer, the brand name for the drug bosentan, which is used to treat pulmonary artery hypertension ("PAH"). (Pls.' Am. Consol. Class Action Compl. & Demand for Jury Trial ["2d Am. Compl."] ¶ 2, ECF No. 74). PAH is a rare and life-threatening disorder that restricts blood flow in the heart and lungs. (Expert Report of Dr. Rachel Damico ["Damico Rept."] at 9–13, ECF No.

---

amicus briefs and often look for guidance to Rule 29 of the Federal Rules of Appellate Procedure, which applies to amicus briefs at the federal appeals level. Id. Rule 29 indicates that amici should state "the reason why an amicus brief is desirable and why the matters asserted are relevant to the disposition of the case." Fed.R.App.P. 29(b)(2). District courts have granted leave to file when amicus curie "provide helpful analysis of the law, they have a special interest in the subject matter of the suit, or existing counsel is in need of assistance." American Humanist Ass'n, 303 F.R.D. at 269 (quotation omitted). On the other hand, if the Court does not find the "proffered information timely and useful," the motion "should not be granted." Id. (quotation omitted). The Court finds that the proposed brief is relevant and helpful and will grant the Motion (ECF No. 314). The Court considers the Amicus Curiae brief in its analysis of the Motion for Summary Judgment.

291-2).[2] Actelion began marketing Tracleer in 2001, (Actelion-Roche License Agreement, ECF No. 303-2), and the patent on Tracleer was set to expire in November 2015, at which point generic drug companies that demonstrated "bioequivalence" with Tracleer would be permitted to enter the market. (Expert Rept. of Todd Clark ["Clark Rept."] ¶¶ 80, 288, ECF No. 303-6).

Tracleer is subject to a Risk Evaluation and Mitigation Strategies ("REMS") program, which the FDA mandates where it determines that additional safety restrictions are necessary for a drug's approval. (Damico Rept. at 22–27). The REMS required that Actelion distribute Tracleer through certain specialty pharmacies and that Tracleer be distributed to REMS compliant patients. (Food & Drug Admin., CDER, Approval Package for Application Number 21-290 at 4, ECF No. 291-11).

Starting in June 2010, various generic drug companies sought to purchase samples of Tracleer from wholesalers, pharmacies, and Actelion directly in order to conduct bioequivalence testing. (6/7/2010 Zydus Ltr. at 2, ECF No. 291-20; 5/6/2013 Zydus Email at 2, ECF No. 303-20; 7/2/2012 Ltr. To Apotex at 2, ECF No. 303-24). In their requests, the generic companies indicated they would be willing to pay market price for Tracleer and comply with any limitations in Tracleer's REMS. (See e.g., 1/21/2011 Ltr. From Apotex at 2, ECF No. 303-21; 6/2010 Ltr. From Zydus at 3, ECF No. 303-22). Actelion, in purported compliance with the REMS program, denied sample requests from these

[2] Citations to page numbers refer to the pagination assigned by the Court's Case Management/Electronic Case Files ("CM/ECF") system.

companies. (See 7/2/2012 Ltr. To Apotex at 2, ECF No. 303-24; 8/9/2012 Ltr. To Roxane at 3, ECF No. 303-25; Expert Report of Keith Webber, Ph.D ["Webber Rept."] ¶¶ 58–64, ECF No. 310-1).

In 2012, Actelion filed a declaratory judgment action against some generic drug companies seeking a judgment that it was not required to provide samples to the generic companies. (Compl. for Declaratory J. at 2–4, ECF No. 291-21). The generic companies filed antitrust counterclaims, which the Court allowed to proceed, and the parties settled with Actelion agreeing to sell Tracleer to some of the generic companies. (10/17/2013 Hrg. Tr., Actelion Pharms. Ltd. et al. v. Apotex, Inc., et al. at 117:19-118:8;, ECF No. 303-27). Generic versions of Tracleer came to market in 2019. (Clark Rept. ¶¶ 175, 189, 227).

B. Procedural Background

Initial Plaintiff Mayor & City Council of Baltimore (the "City") filed its original Complaint against Actelion on November 19, 2018. (ECF No. 1).[3] Upon the City and Government Employees' unopposed Motion for Consolidation and Appointment of Interim Class Counsel, (ECF No. 32), this Court consolidated Government Employees Health Association v. Actelion Pharmaceuticals, Ltd., et al., No. GLR-18-3571 (D.Md. filed Nov. 20, 2018) with the present case on January 18, 2019. (ECF No. 33). On January 25, 2019, the City and Government Employees filed a Consolidated Class Action Complaint and Demand for Jury Trial ("Amended Complaint") on behalf of themselves

[3] The City has since voluntarily dismissed all of its claims against all defendants.

and similarly situated individuals in thirty states and U.S. territories.[4] (ECF No. 34). On September 30, 2019, the Court granted Actelion's Motion to Dismiss Plaintiffs' Amended Complaint for failure to state a claim. (ECF No. 50). The United States Court of Appeals for the Fourth Circuit reversed and remanded the case for further proceedings. (ECF No. 55). The City and Government Employees filed a Second Amended Complaint on July 8, 2021. (ECF No. 74). The forty-six count Second Amended Complaint alleges: unlawful refusals to deal and attempts to monopolize in violation of § 2 of the Sherman Act, 15 U.S.C. § 2 (2018) (Count 1); violations of various state antitrust laws[5] (Counts 2–26); and

[4] Government Employees defined the putative class as "[a]ll persons and entities" in Arizona, California, District of Columbia, Florida, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Utah, Virginia, West Virginia, and Wisconsin "who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price of Tracleer or bosentan, other than for resale, at any time during the period from November 20, 2015 through and until the anticompetitive effects of Defendants' challenged conduct cease . . . ." (Am. Compl. ¶¶ 285–86, ECF No. 34). This class definition remains unchanged in the Second Amended Complaint, as discussed below. (2d Am. Compl. ¶¶ 282–83).

[5] Specifically, Government Employees alleges violations of the: Arizona Uniform State Antitrust Act (Count 2) (2d Am. Compl. ¶¶ 308–15); District of Columbia Antitrust Act (Count 3) (Id. ¶¶ 316–21); Illinois Antitrust Act (Count 4) (Id. ¶¶ 322–27); Iowa Competition Law (Count 5) (Id. ¶¶ 328–32); Maine Antitrust Statute (Count 6) (Id. ¶¶ 333–38); Maryland Antitrust Statute (Count 7) (Id. ¶¶ 339–45); Massachusetts General Statutes (Count 8) (Id. ¶¶ 346–54); Michigan Antitrust Reform Act (Count 9) (Id. ¶¶ 355–60); Minnesota Antitrust Law (Count 10) (Id. ¶¶ 361–66); Mississippi Antitrust Statute (Count 11) (Id. ¶¶ 367–74); Missouri Merchandising Practices Act (Count 12) (Id. ¶¶ 375–80); Nebraska Junkin Act (Count 13) (Id. ¶¶ 381–86); Nevada Unfair Trade Practices Act (Count 14) (Id. ¶¶ 387–95); New Hampshire Antitrust Statute (Count 15) (Id. ¶¶ 396–01); New Mexico Antitrust Act (Count 16) (Id. ¶¶ 402–07); New York General Business Law (Count 17) (Id. ¶¶ 408–13); North Carolina General Statutes (Count 18) (Id. ¶¶ 414–18); North Dakota Uniform State Antitrust Act (Count 19) (Id. ¶¶ 419–24); Oregon Antitrust

violations of various state consumer protections laws[6] (Counts 27–46). (2d Am. Compl. ¶¶ 292–655). Government Employees seeks declaratory, injunctive, and equitable relief. (Id. at 88–141).

The City voluntarily dismissed their claims against all Defendants on December 16, 2021. (ECF No. 101). The remaining Plaintiff, Government Employees, and Actelion engaged in a lengthy discovery process through 2023. On September 6, 2024, the Court certified a class defined as follows:

> All entities that, for consumption by their members, employees, insureds, participants or beneficiaries, purchased,

---

Law (Count 20) (Id. ¶¶ 425–30); Puerto Rican Anti-Monopoly Act (Count 21) (Id. ¶¶ 431–35); Rhode Island Antitrust Act (Count 22) (Id. ¶¶ 436–40); South Dakota Antitrust Statute (Count 23) (Id. ¶¶ 441–46); Utah Antitrust Act (Count 24) (Id. ¶¶ 447–52); West Virginia Antitrust Act (Count 25) (Id. ¶¶ 453–59); and Wisconsin Antitrust Act (Count 26) (Id. ¶¶ 460–68).

[6] Specifically, Government Employees alleges violations of the: Arizona Consumer Fraud Act (Count 27) (2d Am. Compl. ¶¶ 475–83); California Unfair Competition Law (Count 28) (Id. ¶¶ 484–92); District of Columbia Consumer Protection Procedures Act (Count 29) (Id. ¶¶ 493–501); Florida Deceptive and Unfair Trade Practices Act (Count 30) (Id. ¶¶ 502–12); Illinois Consumer Fraud and Deceptive Business Practices Act (Count 31) (Id. ¶¶ 513–20); Massachusetts Consumer Protection Act (Count 32) (Id. ¶¶ 521–29); Minnesota Consumer Fraud Act (Count 33) (Id. ¶¶ 530–39); Montana Unfair Trade Practices and Consumer Protection Act) (Count 34) ((Id. ¶¶ 540–44); Nebraska Consumer Protection Act (Count 35) (Id. ¶¶ 545–53); Nevada Deceptive Trade Practices Act (Count 36) (Id. ¶¶ 554–63); New Hampshire Consumer Protection Act (Count 37) (Id. ¶¶ 564–73); New Mexico Unfair Practices Act (Count 38) (Id. ¶¶ 574–83); North Carolina Unfair Trade and Business Practices Act (Count 39) (Id. ¶¶ 584–92); Oregon Unlawful Trade Practices Act (Count 40) (Id. ¶¶ 593–603); Rhode Island Deceptive Trade Practices Act (Count 41) (Id. ¶¶ 604–16); South Carolina Unfair Trade Practices Act (Count 42) (Id. ¶¶ 617–25); South Dakota Deceptive Trade Practices and Consumer Protection Law (Count 43) (Id. ¶¶ 626–35); Vermont Consumer Fraud Act (Count 44) (Id. ¶¶ 636–41); Virginia Consumer Protection Act (Count 45) (Id. ¶¶ 642–48); and West Virginia Consumer Credit and Protection Act (Count 46) (Id. ¶¶ 649–55).

> paid and/or provided reimbursement for some or all of the purchase price of Tracleer or bosentan, other than for resale, in the Class States and territories[7] at any time during the period from December 29, 2015, through and until the anticompetitive effects of Defendants' challenged conduct cease.[8]

(9/6/2024 Order at 1–2, ECF No. 350). On February 6, 2024, Actelion filed a Motion for Summary Judgment. (ECF No. 291). Government Employees filed an Opposition on March 21, 2024, (ECF No. 303), and Actelion filed a Reply on April 24, 2024, (ECF No. 325).

II. DISCUSSION

A. Standard of Review

In reviewing a motion for summary judgment, the Court views the facts in a light most favorable to the nonmovant, drawing all justifiable inferences in that party's favor. Ricci v. DeStefano, 557 U.S. 557, 586 (2009) (quoting Scott v. Harris, 550 U.S. 372, 380 (2007)); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) (citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 158–59 (1970)). Summary judgment is proper when the movant demonstrates, through "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials," that "there is no

[7] The Class States and territories consist of: Arizona, California, Florida, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, West Virginia, Wisconsin, the District of Columbia, and Puerto Rico.

[8] The following are excluded from the Class: (1) Defendants and their subsidiaries and affiliates; and (2) Federal and state governmental entities.

genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a), (c)(1)(A). Significantly, a party must be able to present the materials it cites in "a form that would be admissible in evidence," Fed.R.Civ.P. 56(c)(2), and supporting affidavits and declarations "must be made on personal knowledge" and "set out facts that would be admissible in evidence," Fed.R.Civ.P. 56(c)(4).

Once a motion for summary judgment is properly made and supported, the burden shifts to the nonmovant to identify evidence showing there is genuine dispute of material fact. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). The nonmovant cannot create a genuine dispute of material fact "through mere speculation or the building of one inference upon another." Othentec Ltd. v. Phelan, 526 F.3d 135, 141 (4th Cir. 2008) (quoting Beale v. Hardy, 769 F.2d 213, 214 (4th Cir. 1985)).

A "material fact" is one that might affect the outcome of a party's case. Anderson, 477 U.S. at 248; see also JKC Holding Co. v. Wash. Sports Ventures, Inc., 264 F.3d 459, 465 (4th Cir. 2001) (citing Hooven-Lewis v. Caldera, 249 F.3d 259, 265 (4th Cir. 2001)). Whether a fact is considered to be "material" is determined by the substantive law, and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248; accord Hooven-Lewis, 249 F.3d at 265. A "genuine" dispute concerning a "material" fact arises when the evidence is sufficient to allow a reasonable jury to return a verdict in the nonmoving party's favor. Anderson, 477 U.S. at 248. If the nonmovant has failed to make a sufficient showing on an essential element of his case where he has the burden of proof,

"there can be 'no genuine [dispute] as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986) (quoting Anderson, 477 U.S. at 247).

B. Analysis

1. Violation of Sherman Act and Analogous State Law

Actelion argues that it is entitled to summary judgment on Government Employees' claims that Actelion violated Section 2 of the Sherman Act and analogous state statutes. Section 2 of the Sherman Act prohibits monopolization and attempts to monopolize the relevant market. 15 U.S.C. § 2 (2012). To state a monopolization claim, a plaintiff must show "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481 (1992) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966)).

a. Anticompetitive Conduct

It is undisputed that Actelion possessed monopoly power. The parties disagree on whether Actelion engaged in anticompetitive conduct to maintain its monopoly power. Actelion argues that it did not engage in anticompetitive conduct in denying sample requests because it had a legitimate business justification for denying sample requests—namely that the FDA-mandated REMS program restricted distribution. (Def.'s Mem. Supp.

Mot. Summ. J. ["Mot."] at 21–27, ECF No. 291-1). Government Employees counters that the REMS program did not require Actelion to block samples and that Actelion's purported concern about REMS compliance is pretextual. (Pls.' Resp. Opp'n Def.'s Mot. Summ. J. ["Opp'n"] at 19–28, ECF No. 303). The Court finds that there are disputes of material fact as to whether Actelion engaged in anticompetitive conduct to maintain its monopoly power, and summary judgment must be denied.

The record is not clear as to whether the REMS program prevented Actelion from providing samples to generic manufacturers. Actelion argues that "[u]nder the unambiguous terms of the REMS, Actelion could only distribute Tracleer through certified specialty pharmacies to patients that were enrolled in the REMS program with (1) prescriptions from REMS-certified physicians, and (b) who underwent the required testing." (Mot. at 24; Approval Package for Application Number 21-290 at 2, ECF No. 291-11). Actelion's expert, Dr. Shimer, explains that there were no exceptions to the REMS requirements for the distribution of Tracleer for bioequivalence testing. (Expert Rept. of Martin H. Shimer ["Shimer Rept"]. ¶¶ 86–87, ECF No. 291-8).[9] Government Employees'

[9] While Government Employees objects to the admission of some of Dr. Shimer's expert testimony, it does not object to this point. (See Mem. Supp. Mot. Exclude Certain Opinions of Martin Shimer and Sean Nicholson, Ph.D, ECF No. 293-1). Government Employees takes issue with Dr. Shimer's statements that the Tracleer REMS prohibited Actelion from providing samples to generics. (Id. at 15–18). Government Employees raises no issue with Dr. Shimer's statement that the Tracleer REMS did not contain explicit exceptions to the REMS distribution requirements. (See generally id.). Accordingly, the Court need not address Government Employees' Daubert Motion as to Dr. Shimer to resolve this summary judgment Motion. The Court defers ruling on the Daubert Motion (ECF No. 293).

expert, Dr. Webber, opines that the REMS program for Tracleer did not require Actelion to erect a samples blockade. (Webber Rept. ¶¶ 13–14). The record also includes FDA and Congressional guidance which tends to demonstrate that the REMS program may not have prevented Actelion from selling its product to generic companies. (See 9/2010 FDA Draft Guidance on Bosentan, ECF No. 303-50 (discussing expectation for bioequivalence testing); see also 21 U.S.C. § 355-1(f)(8) (prohibiting use of REMS "to block or delay" generic drug development); FDA Guidance on "How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD" at 2, ECF No. 303-53 (stating that "requesting or obtaining" a FDA approval letter for generic drug applications is "not a legal requirement")). Because there are disputes of material fact as to whether the REMS program prevented Actelion from providing samples to generic manufactures, the Court cannot say that Actelion's purported compliance with the REMS program was a legitimate business justification, and summary judgment is "inappropriate." See Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 483 (1992).

The record is also inconclusive as to whether Actelion's purported concern about REMS compliance was pretextual. Actelion's internal documents demonstrate that it may have had an internal policy of using regulatory requirements to maintain monopoly power. (See, e.g., Actelion Tracleer Early-LoE Project Presentation at 12–13, ECF No. 303-57 (indicating goal of "extend[ing] exclusivity"); see also id. at 24 (listing "[r]egulatory requirements" to "maintain[] assets despite [] loss of exclusivity")). The record also

contains evidence that, despite its purported REMS compliance concerns, Actelion provided Tracleer samples to academic researchers without requiring them to adhere to the REMS. (See 9/27/2022 Dep. of Ryan Harris ["Harris Dep."] at 88:22-89:8, ECF No. 303-64). Actelion may also have indicated that its purported goal of complying with REMS was pretextual when it wrote in denying a generic company's sample request that "Actelion's right to refuse to do business with [generic company] Apotex is not premised on the existence of the Tracleer REMS" (5/30/2013 Actelion Email at 1, ECF No. 303-26) (emphasis in original). In short, there is "ample evidence to support a finding that the Defendants' proffered 'legitimate business purposes' are pretextual," and summary judgment must be denied. Microbix Biosystems, Inc. v. Biowhittaker, Inc., 172 F.Supp.2d 680, 693–96 (D.Md. 2000), aff'd, 11 F.App'x 279 (4th Cir. 2001) (denying summary judgment with respect to Sherman Act liability).

Actelion relies on Mylan v. Celgene, 2018 WL 11299447 (D.N.J. Oct. 3, 2018), and Natco Pharma, Ltd. v. Gilead Sciences, Inc., 2015 WL 5718398 (D.Minn. Sept. 29, 2015), in arguing that it is entitled to summary judgment on Government Employees' Sherman Act and state law claims. As an initial matter, neither out-of-circuit, unreported case is binding on this Court. Additionally, the cases are factually distinguishable from this case. Unlike Mylan and Natco, the record here contains evidence that Actelion's purported compliance with the REMS program may have been a strategic tactic to delay generic competition and pretextual. (See, e.g., 5/30/2013 Actelion Email at 1; Harris Dep. at 88:22–89:8; Actelion Tracleer Early-LoE Project Presentation at slide 12–13). Further, the Mylan

court denied summary judgment in part where, as here, the drug manufacturer refused to sell samples to generic companies after the generic company received FDA approval of its bioequivalence testing protocols. Mylan, 2018 WL 11299447, at *16–19 (D.N.J. Oct. 3, 2018); (See Webber Rept. ¶¶ 58–64; 5/30/2013 Actelion Email at 1).[10]

A reasonable jury could find that the REMS program did not require a samples blockade or that Actelion's claimed reliance on the REMS program is pretextual. As such, the Court will deny Actelion's Motion for Summary Judgment as to whether Actelion engaged in anticompetitive conduct in violation of the Sherman Act and equivalent state laws.

b. Antitrust Injury

Actelion also argues that it is entitled to summary judgment on Government Employees' Sherman Act and state law equivalent claims because Government Employees cannot show antitrust injury. (Mot. at 30–35). Actelion maintains that because the Tracleer REMS posed an independent legal or regulatory bar to generic entry, the REMS is the "true cause" of any harm to Government Employees. (Id. at 31). As discussed above, the record does not establish that the Tracleer REMS prohibited Actelion from providing samples to generic drug companies. It is a question of material fact whether Government Employees'

[10] Actelion also submitted a Notice of Supplemental Authority regarding In re Revlimid & Thalomid Purchaser Antitrust Litigation, No. 21-20451, 2024 WL 2861865 (D.N.J. June 6, 2024), where "the court dismissed antitrust claims based on, among other things, refusal to provide samples of a drug covered by an FDA-mandated REMS." (Notice of Supp. Authority Relating to Def.'s Mot. Summ. J. at 1, ECF No. 341). The Court is similarly not persuaded by this out of circuit, unreported case. The Revlimid opinion addressed a motion to dismiss and did not present the disputed material facts present here.

injury flowed directly from the REMS regulation or from Actelion's allegedly anticompetitive scheme.

Actelion further argues that Government Employees cannot establish antitrust injury because its theory of causation is disputed by the record. (Id. at 32–35). Actelion characterizes Government Employees' claims as a challenge to Actelion's initial refusal to provide samples when generic companies requested such samples from Actelion. (Id.). Actelion maintains that based on this theory of injury, the generic entry date Government Employees puts forward for when generic companies would have acquired samples absent Actelion's alleged misconduct is wrong. (Id.). Government Employees counters that it challenges Actelion's years-long anticompetitive scheme, which included exclusionary contracts with the pharmacies dispensing Tracleer, and not just Actelion's refusal to provide samples to generic companies when requested. (Opp'n at 33–35). The Fourth Circuit recently instructed that "a firm's exclusionary efforts" must be "considered in their totality" in Sherman Act § 2 cases. Duke Energy Carolinas, LLC v. NTE Carolinas II, LLC, 111 F.4th 337 2024 WL 3642432, at *355 (4th Cir. 2024). Government Employees cites to evidence from the record to demonstrate that the generic companies sought to purchase Tracleer through other channels before requesting samples from Actelion directly. (Opp'n at 34–35 (citing 11/11/2009 Zydus Email, ECF No. 303-29; 1/12/2011 Actavis Email, ECF No. 303-30; Clark Rept. ¶¶ 111, 285, n. 423, ECF No. 303-6; 3/12/2009 Mylan Email, ECF No. 303-19; 8/17/2011 Par Email, ECF. No. 303-43)). This dispute boils down to one question: when would generic companies have been able to enter the market absent

Actelion's alleged anticompetitive conduct. This is a question of material fact which should be left to the jury, and summary judgment is inappropriate.

Based on the foregoing, the Court concludes that the record evidence creates genuine disputes of material facts as to whether Actelion willfully maintained its monopoly power in the relevant market, in violation of section 2, and as to when and if Government Employees' injuries were caused by Actelion's alleged misconduct. Accordingly, the Court will deny Actelion's Motion for Summary Judgment as to Government Employees' Sherman Act and equivalent state law claims.

2. Duty to Deal

Actelion separately argues that it is entitled to summary judgment on Government Employees' claims because it had no duty to deal with generic manufacturers. (Mot. at 27–30). Government Employees counters that by refusing to sell to generic companies, Actelion violated duty to deal law. (Opp'n at 28–32). The Court finds that there are questions of material fact as to whether Actelion violated duty to deal law and will deny summary judgment.

The Supreme Court has articulated that the Sherman Act "does not restrict the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." United States v. Colgate & Co., 250 U.S. 300, 307 (1919). However, this right is not "unqualified." Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004) (quoting Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585,

601 (1985)). "Under certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2." Trinko, 540 U.S. 398, 408. These circumstances include refusals to deal that are "conceived in monopolistic purpose or market control." Times-Picayune Publ'g Co. v. United States, 345 U.S. 594, 625 (1953).

The Trinko Court explained that refusal to deal has been found unlawful where a company that is "already in the business of providing a service to certain customers . . . refused to provide the same service to certain other customers." Trinko, 540 U.S. at 398 (citing Otter Tail Power Co. v. United States, 410 U.S. 366, 370–71, 377–78 (1973)). Here, Actelion was already selling Tracleer to other customers, and a jury could find that Actelion's refusal to sell Tracleer to some customers (generic companies) while selling it to others was anticompetitive in violation of the Sherman Act § 2.

A jury could additionally find that Actelion's refusal to deal was for a monopolistic purpose in violation of § 2. The record establishes that the generic companies offered to pay fair market value for Tracleer samples. (See e.g., 9/21/2022 Dep. of Carla Calabro Par ["Par Dep"]. at 87:22–88:5, ECF No. 303-16). The Supreme Court has found liability for refusal to deal with rivals where a company was "willing to sacrifice short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival." Aspen Skiing, 472 U.S. at 610–11. The Court has already found that the record is inconclusive as to whether Actelion legitimately thought the Tracleer REMS program prevented selling samples to a generic company. A jury could find that Actelion's refusal to sell its product at fair-market value would not make economic sense absent a goal of

maintaining a monopoly. Such a finding could constitute an unlawful refusal to deal in violation of the Sherman Act § 2.

Actelion presents an additional argument that a refusal to deal is "not actionable absent a prior history of dealing between the parties." (Mot. at 28). The Fourth Circuit has never articulated a prior history of dealing requirement, and courts in other cases involving refusal to provide samples of drugs under a REMS program have held that a prior course of dealing "is relevant but not dispositive in determining whether such a duty applies." Mylan, 2014 WL 12810322, at *5; see also Otter Tail, 410 U.S. 366 (imposing liability for refusal to deal even where there was no prior course of dealing between the parties).[11]

In short, a reasonable jury could find that by refusing to sell samples to generic companies, Actelion engaged in anticompetitive conduct in violation of the Sherman Act § 2. The Second Circuit recently affirmed that a defendant was liable for monopolization where the defendant, through exclusive supply agreements, "prevented generic drug companies from getting access to the quantity of Daraprim they needed to conduct testing demanded by the [FDA]." Fed. Trade Comm'n v. Shkreli, 581 F.Supp.3d 579, 590 (S.D.N.Y. 2022), aff'd, 2024 WL 1026010 (2d Cir. Jan. 23, 2024). Government Employees has proffered evidence sufficient to raise numerous issues of material fact from which a reasonable jury could find that Actelion engaged in anticompetitive conduct which caused

[11] Because the Court finds that Actelion's conduct could fall within other exceptions to its general right to choose whom to deal with, the Court need not consider Actelion's argument that the essential facilities doctrine, which has been called into question by the Supreme Court, does not apply. See Trinko, 540 U.S. at 410–11.

injury to Government Employees. As such, the Court must deny Actelion's Motion for Summary Judgment.

III. CONCLUSION

For the foregoing reasons, Actelion's Motion for Summary Judgment (ECF No. 291) will be denied. The pending Daubert Motions (ECF Nos. 287, 289, 293) will be denied as moot without prejudice to being reasserted at trial. A separate Order follows.

Entered this 6th day of September, 2024.

/s/
George L. Russell, III
Chief United States District Judge